CTEP Simplified Disease Classification Overview

The *CTEP Simplified Disease Classification* (CTEP SDC) v1.0 is a restructured, more intuitive classification of diseases, designed to meet the needs of CTEP while still allowing reporting based on the Medical Dictionary for Drug Regulatory Reporting (MedDRA) v6.0 disease terminology. It was developed to make reporting of clinical trials data more standardized and to facilitate uniform reporting by CTEP of its clinical trials activities.

Based on current clinical trials supported by CTEP, the CTEP SDC reduces the number of diseases from over 1,000 to just under 250 terms. It also reduces the number of groupings to about one-half the current categories and subcategories. This reduction is expected to improve the navigation of the disease hierarchy resulting in greater reporting consistency by broad disease groupings and individual diseases. It also introduces the World Health Organization's (WHO) terms for hematologic diseases, and provides a more simplified hierarchical organization of these terms.

The CTEP SDC is designed to uniquely identify the specific histologies for which CTEP conducts clinical trials, and groups these specific histologies into a hierarchy that conforms to the current organization of clinical oncology research. The CTEP SDC includes three levels, the lowest of which is the CTEP Disease Term, which is generally based on histology, but does not include concepts such as clinical stage or the extent of prior therapy allowable for patients who are eligible on a clinical study. This is a key distinction between the CTEP SDC and the currently used MedDRA terminology. MedDRA incorporates multiple clinical concepts into its disease terms (e.g., histology, stage, and/or prior therapy), creating a more comprehensive disease terminology, but one that prevents the coding of stage and prior therapy information as distinctive concepts. This, as well as the distinctive concept coding of molecular characteristics of cancers eligible on studies, is a future goal of the CTEP Enterprise System.

The CTEP SDC is available in the following formats:

Text (.txt) file	The text file is a colon delimited file that lists the CTEP SDC codes and is used for importing the codes into user databases.
Excel (.xls) file	The Excel file lists the CTEP SDC codes.
Mapping Version Excel (.xls) file	The Excel mapping file provides the mapping of MedDRA Disease Terms to the CTEP SDC for use during a one-time conversion of disease information within the CTEP Enterprise System. In addition, each CTEP Disease Term is mapped to a single MedDRA term for use when reporting to the Food and Drug Administration.

The CTEP SDC will have bearing on several of the CTEP data systems as listed below.

Adverse Event Expedited Reporting System (AdEERS)	AdEERS was first introduced using an abbreviated disease hierarchy and will be migrated to the CTEP SDC by January 1, 2005.
Clinical Data Update System (CDUS)	To improve the ability to track accrual to CTEP-supported studies, the patient's disease must now be submitted using the CTEP SDC, regardless of CDUS monitoring assignment (i.e., abbreviated vs. complete) for all studies approved on or after 10/1/04.

Submissions of patient disease data for studies approved prior to 10/1/04 and assigned to:

- **CDUS-Abbreviated Monitoring**

  Although previously unrequired, sites may now choose to submit patient disease data using the CTEP SDC.

- **CDUS-Complete Monitoring**

  Sites may choose to switch to the CTEP SDC or continue using the MedDRA v6.0 disease hierarchy. If the CTEP SDC is selected, then all patient-specific disease codes submitted for the study must originate from the CTEP SDC.

Important: In either situation above, if the CTEP SDC is selected for the submission of patient disease data, then CTEP must receive advance notice, via the NCI CTEP Help Desk, prior to initial submission. No further action is necessary for studies continuing the use of MedDRA as the source of patient disease codes.

Studies Assigned or Converting to CTEP SDC:

Additional business rules will be built into the CDUS Smartloader to assure that all patients accrued to the study meet one of the diseases being studied on the trial (e.g., only breast cancer patients can be accrued to a breast cancer trial). Phase 1 trials, where accrual of patients with various diseases is expected, will be exempt from this validation check.

The abstracted CTEP SDC disease codes valid for each study will be included as a standard in the List of Codes which is sent to sites prior to submission due date.

Studies Submitting via CDUS Web:

Studies with an approval date on or after 10/1/04 will be assigned to the CTEP SDC. Those approved prior to 10/1/04 will be mapped to the CTEP SDC. CTEP SDC values will be available from the CDUS Web beginning mid-December 2004.

PIO-related Correspondence

Protocol Submission Worksheet (PSW) - Disease terms used will be consistent with the CTEP SDC to minimize potential delays during the CTEP protocol review process.

NOTE: Submitted PSWs that do not use the CTEP SDC will not be returned, but may incur delays during the review process.